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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,657	09/04/2003	David J. Burke	A-72167-1	8319

32940 7590 01/26/2005

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EXAMINER
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YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/656,657	Applicant(s) BURKE ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.  
2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-14 is/are pending in the application.  
4a) Of the above claim(s) 2-5 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 6-14 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/19/03</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

**Acknowledgment of Papers Received:** Response to Restriction Requirement and Amendments dated 10/25/04.

#### ***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 1, drawn to an oxidized collagen, classified in class 530, subclass 350.
  - II. Claims 2-5, drawn to a pharmaceutical formulation comprising a drug and collagen, classified in class 424, subclass 488.
  - III. Claims 6-14, drawn to a pharmaceutical formulation comprising a drug, collagen, and oxidized collagen, classified in class 424, subclass 488.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to separate inventions. The invention of group II is a pharmaceutical formulation requiring a drug, while the invention of group I is drawn to an oxidized collagen produce with no specific use, pharmaceutical or otherwise. Although the oxidized collagen of group I represents a possible species of the collagen of groups II and III, the inventions of groups II and III require drugs, while the collagen can be used in a food or cosmetic product.
3. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

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inventions the invention of group III requires an oxidized collagen while the invention of group II does not. The inventions are unrelated also due to the compatibility of certain pharmaceutical agents. The inclusion of oxidized collagen to the formulation of group III allows for a separate and wider range of drugs useful in the formulation. These agents would not be compatible with the formulation of group II, therefore the inventions of group II and II cannot be used together and are unrelated.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Claims 2-5 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group I, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/24/04.

7. Applicant's election without traverse of group II in the reply filed on 10/24/04 is acknowledged.

### ***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 6-14 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-11 of U.S. Patent No. 6,673,370 in view of Rosenthal et al (USPN 5,700,477 hereafter '477). The claims of the instant invention are drawn to a composition comprising collagen, a drug and an oxidized collagen wherein a thiomethyl group of one or more methionine residues of the collagen have been replaced by methylsulfoxy and/or methylsulfonyl groups. The '370 patent is drawn to a similar composition without collagen. However the combination of various kinds of collagen is well within the level of skill in the art as seen in the '477 patent which discloses a three dimensions matrix useful for drug delivery (abstract). The matrix is a mixture of different materials that provides conduits or pathways for the pharmaceutical agents to migrate and allow for cellular invasion (examples). The matrix is a mixture of bioabsorbable substances so that it can provide a better implant material for wound healing. A skilled artisan would be motivated to include collagen into the formulation of '370 patent in order to provide a better support matrix to be useful in drug delivery for wound healing.

***Conclusion***

Claim 1 has been canceled and claims 2-5 have been withdrawn from consideration. Claims 6-14 have been rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MP Young

Micah-Paul Young  
Examiner  
Art Unit 1615

  
THURMAN K. PAGE  
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